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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/623,990 | 07/21/2003 | Preeti Lal | PF-0487-2 DIV | 5520 |

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| EXAMINER | |
|---|---|
| RAO, MANJUNATH N | |
| **ART UNIT** | **PAPER NUMBER** |
| 1652 | |

DATE MAILED: 01/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/623,990 | LAL ET AL. | |
| | Examiner | Art Unit | |
| | Manjunath N. Rao, Ph.D. | 1652 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *20 May 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-29* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-29, 56-57 are currently pending in this application. Claims 30-55 have been cancelled by the applicant (see transmittal sheet).

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 17-18 and 56, drawn to isolated polypeptide with an amino acid sequence SEQ ID NO:1, classified in class 435, subclass 183.

II. Claims 3-7, 9-10, 12-13, 57, drawn to an isolated polynucleotide with SEQ I DNO:2, vector, host cells and method of making the polypeptide, classified in class 435, subclass 69.1.

III. Claim 8, drawn to a transgenic organism, classified in class 800, subclass 8.

IV. Claim 11, drawn to an antibody, classified in class 530, subclass 387.1.

V. Claims 14-16, drawn to a method of detecting a target polynucleotide by hybridization or PCR, classified in class 435, subclass 6.

VI. Claim 19, drawn to a method treating using the polypeptide, classified in class 424, subclass 94.1.

VII. Claim 20, 27, drawn to a method of screening a compound for agonist activity, classified in class 435, subclass 4.

VIII. Claim 21, drawn to a composition comprising the agonist, classified in class 514, subclass 789.

IX. Claim 22, drawn to a method of treating a disease condition using the agonist compound, classified in class 424, subclass unknown.

X. Claim 23, 27 drawn to a method of screening a compound for its antagonistic characteristic, classified in class 435, subclass 4.

XI. Claim 24, drawn to a composition comprising the antagonistic compound, classified in class 514, subclass 789.

XII. Claim 25, drawn to a method of treating a disease condition using the antagonist compound, classified in class 424, subclass unknown.

XIII. Claim 26, drawn to a method of screening for a compound that specifically binds to the polypeptide, classified in class 435, subclass 4.

XIV. Claim 28, drawn to a method of screening for a compound that alters the expression of the polynucleotide, classified in class 435, subclass 6.

XV. Claim 29, drawn to a method of screening for potential toxicity of a compound to a biological sample containing the nucleic acids, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III, IV, VIII, XI are patentably distinct from each other. The polypeptide of group I, the polynucleotide of group III, the transgenic organism of Group III, and the antibody of group IV, the agonist and antagonist compounds of groups VIII and XI each comprise amino acid sequences and nucleotide sequences and compounds whose chemical structure is unknown. The compounds are chemically unrelated, do not require each other for practice; have separate utilities, such as use of the group I, polypeptides to raise specific antibodies versus the use of

polynucleotides in a hybridization reaction versus the use of agents in controlling the expression of a polynucleotide or the activity of the polypeptide and are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Inventions V through VII, IX, X, XII through XV are all patentably distinct methods differing from each other. These are different methods with separate steps, separate requirements and having different outcomes. They are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Invention I and inventions VI, VII, X, XIII, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides can be used to raise specific antibodies as opposed to its use in the methods of groups VI, VII, X, XIII.

Inventions I and inventions V, IX, XII, XIV-XV are distinct from each other. Invention I is neither used nor made in any of the method of groups V, IX, XII, XIV-XV. They are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Invention II and invention V, XIV, XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides can be used to make a recombinant polypeptide as opposed to its use in the method of groups V, XIV, XV.

Invention II and inventions VI-VII, IX, XI-XIII, XV are distinct from each other. Invention II is neither used nor made in any of the method of groups VI-VII, IX, XI-XIII, XV. They are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Inventions IV and inventions X, XII, XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody can be used to affinity purify the polypeptide as opposed to its use in the methods of groups X, XII, XIII.

Inventions IV and inventions V-VII, XIV-XV are distinct from each other. Invention IV or V is neither used nor made in any of the method of groups V-VII, XIV-XV. They are subject

to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Invention VIII and invention IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the agonist can be used to control the activity of the polypeptide in vitro as opposed to its use in the methods of group IX.

Invention VIII and inventions V-VII, X, XII-XV are distinct from each other. Invention VIII is neither used nor made in any of the method of groups V-VII, X, XII-XV. They are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Invention XI and invention XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the agonist can be used to control the activity of the polypeptide in vitro as opposed to its use in the methods of group XII.

Invention XI and inventions V-VII, IX-X, XIII-XV are distinct from each other. Invention VIII is neither used nor made in any of the method of groups V-VII, IX-X, XIII-XV. They are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Rejoinder of restricted inventions***

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR

1.312. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. **Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112.** Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. **Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined.** See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to rejoin, in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The Examiner can normally be reached on 7.00 a.m. to 3.30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of

this application or proceeding should be directed to the receptionist whose telephone number is

571-272-1600.

Manjunath N. Rao, Ph.D.
Primary Examiner
Art Unit 1652

January 9, 2006